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10/562,902	11/22/2006	Daniel Licari	71247-0051	3860

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	PAPER NUMBER
1657	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,902	LICARI ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/05/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the group I, claims 1-10, in the reply filed on 4/10/2009 is acknowledged. The traversal is on the ground(s) that the cited US 6,924,273 does not disclose a composition comprising sodium chloride and hyaluronic acid and, thus, the prior art cannot be considered as teaching "special technical feature". This is not found persuasive because upon review of the reference it is not found true. For example: US 6,924,273 explicitly discloses both sodium chloride and hyaluronic acid in a pharmaceutical composition, for example: col. 9, lines 47 and 56. The requirement is still deemed proper and is therefore made FINAL.

Claims 11-14 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 4/10/2009.

Claims 1-10 are under examination in the instant office action.

Claim Objections

Claims 1-10 are objected to because of the following informalities:

First independent claim starts with article "A" and depending claims start with article "The". Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by phrase "wherein it contains" because "it" does not clearly points out antecedent basis and, in the instant case, "it" could be either medium, base, organ, tissue or cell. It is suggested to clearly write, for example: "wherein the medium contains…". The same/similar rejection is applied to claims 2-10. With respect to the phrase "in addition" (claims 3, 5, 9) it is noted that the claim language fails point out to what and/or in which way some additional components are added. It is suggested to write, for example: "wherein the medium further contains…".

Claims 2, 4, 6 and 8 are rendered indefinite by the phrases "preferentially", "preferably". A broad range or limitation followed by linking terms and a narrow range or limitation within the broad range or limitation is considered indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. MPEP 2173.05(c).

With respect to claim 9 it is uncertain whether all or some of the listed components are incorporated into the medium as intended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by DERWENT publication XP 002036193 of JP 6107538 (IDS reference).

Claims are directed to a preservation medium for living organs, biological tissues, and cells wherein the medium comprises a liquid nutritive base, a high-molecular-weight hyaluronic

acid and sodium chloride and wherein the medium is free from components of animal origin. Some claims are further drawn to the amounts of hyaluronic acids 80-4,000 mg/L or 100-200 mg/L or 100-160 mg/L, to the amounts of sodium chloride 4,500-9,000mg/L or 5,500-9,000mg/L or 7,000 mg/L of sodium chloride in the medium. Some claims are further drawn to the medium osmolarity being from 300- 465 mOsm +/- 40 mOsm. Some claims are further drawn to the medium Brookfield viscosity at 20 °C in the range between 1-15 centipoises or 2.5-10 centipoises. Some claims are further drawn to incorporation of trace elements, amino acids, vitamins, pH buffer stabilizers into the medium. Some claims are further drawn to the exclusion of dextran.

The DERWENT publication XP 002036193 of JP 6107538 discloses a preservation medium for living organs, tissues and cells of eye ball cornea transplant wherein the medium comprises a liquid nutritive base, a high-molecular-weight hyaluronic acid and sodium chloride and wherein the medium is free from components of animal origin (see DERWENT abstract). The cited medium as disclosed contains 0.05-05 % (500-5000 mg/L) of hyaluronic acid (HA), abut 5 g/L or 0.5 % of sodium chloride. The medium has osmolarity of about 260-350 mOsm. The medium also contains salts or trace elements and pH buffer stabilizer or buffering agents. The cited reference explicitly teaches that dextran was not used in the medium and that the exclusion of dextran provides for similar or superior effects. The cited medium contains same components in the same amounts as required for the claimed medium and, therefore, it is reasonably expected to present identical viscosity as intended for the claimed medium. Thus, the cited document anticipates the claimed invention.

Claims 1, 2 and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/32929 (IDS reference).

Claims are directed to a preservation medium for living organs, biological tissues, and cells wherein the medium comprises a liquid nutritive base, a high-molecular-weight hyaluronic acid and sodium chloride and wherein the medium is free from components of animal origin. Some claims are further drawn to the amounts of hyaluronic acids 80-4,000 mg/L or 100-200 mg/L or 100-160 mg/L, to the amounts of sodium chloride 4,500-9,000mg/L or 5,500-9,000mg/L or 7,000 mg/L of sodium chloride in the medium. Some claims are further drawn to incorporation methyl cellulose in the medium in amounts 210-5,000 mg/L or 1,900-2,500 mg/L or 2,205 mg/L. Some claims are further drawn to the medium osmolarity being from 300- 465 mOsm +/- 40 mOsm. Some claims are further drawn to the medium Brookfield viscosity at 20 °C in the range between 1-15 centipoises or 2.5-10 centipoises. Some claims are further drawn to incorporation of trace elements, amino acids, vitamins and/or pH buffer stabilizers into the medium. Some claims are further drawn to the exclusion of dextran.

WO 96/32929 discloses an ophthalmic solution or a preservation medium for living organs, biological tissues and cells wherein the medium comprises a liquid nutritive base, a high-molecular-weight HA and sodium chloride and wherein the medium is free from components of animal origin (entire document). The cited medium contains HA in amounts 0.1-5 % (page 5, last par. or page 7, par. 3), sodium chloride in amounts 0.01-1% (page 7). The medium osmolarity is in the range 200-600 mOsm (page 7). The cited document also teaches incorporation of methyl cellulose (page 14, line 4-5) in the medium in amounts 0.1-5% (page 14, lines 4-6). The medium also contains salts or trace elements and pH buffer stabilizer or buffering agents. The dextran is

absent. The cited medium contains same components in the same amounts as required for the claimed medium and, therefore, it is reasonably expected to present identical viscosity as intended for the claimed medium. Thus, the cited document WO 96/32929 anticipates the claimed invention.

Claims 1-4 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,102,783 (Alkemade et al).

Claims are directed to a preservation medium for living organs, biological tissues, and cells wherein the medium comprises a liquid nutritive base, a high-molecular-weight hyaluronic acid and sodium chloride and wherein the medium is free from components of animal origin. Some claims are further drawn to the amounts of hyaluronic acids 80-4,000 mg/L or 100-200 mg/L or 100-160 mg/L, to the amounts of sodium chloride 4,500-9,000mg/L or 5,500-9,000mg/L or 7,000 mg/L of sodium chloride in the medium. Some claims are further drawn to incorporation of 200-75,000 mg/L or 450- 50,000 mg/L of poloxamer 188 in the medium. Some claims are further drawn to the medium osmolarity being from 300- 465 mOsm +/- 40 mOsm. Some claims are further drawn to the medium Brookfield viscosity at 20°C in the range between 1-15 centipoises or 2.5-10 centipoises. Some claims are further drawn to incorporation of trace elements, amino acids, vitamins, pH buffer stabilizers into the medium. Some claims are further drawn to the exclusion of dextran.

US 5,102,783 (Alkemade et al) (same disclosure as in the IDS reference WO 92/21234) teaches a preservation medium for living organs, biological tissues and cells (entire document), wherein the medium comprises high-molecular-weight HA in amounts 10 mg/L – 10,000 mg/L

(col. 5, lines 60-68) including sodium hyaluronate form when dissolved in balanced salt solution (table at col. 6). The cited document teaches incorporation of a liquid nutritive base that is either balanced salt solution or a conventional medium Ham's F-10, for example: col. 4, line 23. The medium Ham's 10 contains sodium chloride in amounts about 0.7% or 7400 mg/L (ATCC catalogue page 518). The balanced salt solution or the conventional media including Ham's F-10 that are incorporated in into the final preservation medium also contains trace elements, amino acids, pH buffering agents within the meaning of the claims. The osmolarity of cited medium that is based on ingredients and amounts of conventional cell culture media and it would fall within the physiologically acceptable ranges as claimed (col. 4, lines 30-35). The cited document teaches that HA provides for viscosity in the medium (col. 5, lines 28-38) and, thus, it would be reasonably to expect that the viscosity of the cited medium is the same as claimed because the cited document teaches the use of the same HA amounts as required for the claimed invention. US 5,102,783 further teaches incorporation of poloxamer 188 in amounts from 0.05 mg/ml or 50 mg/L to 10 mg/ml or 10,000 mg/L (col. 6, lines 23-29). The dextran is absent. US 5,102,783 explicitly teaches substitution of HA for serum that is a component of animal origin for the benefit in reducing potential microbial and viral contamination.

The cited medium contains same components in the same amounts as required for the claimed medium and, therefore, it is reasonably expected to present identical viscosity as intended for the claimed medium.

Thus, the cited document US 5,102,783 anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over DERWENT publication XP 002036193 of JP 6107538 (IDS reference), WO 96/32929 (IDS reference) and US 5,102,783 (Alkemade et al).

Claims are directed to a preservation medium for living organs, biological tissues, and cells wherein the medium comprises a liquid nutritive base, a high-molecular-weight hyaluronic acid and sodium chloride and wherein the medium is free from components of animal origin. Some claims are further drawn to the amounts of hyaluronic acids 80-4,000 mg/L or 100-200 mg/L or 100-160 mg/L, to the amounts of sodium chloride 4,500-9,000mg/L or 5,500-9,000mg/L or 7,000 mg/L of sodium chloride in the medium. Some claims are further drawn to incorporation of 200-75,000 mg/L or 450- 50,000 mg/L of poloxamer 188 in the medium. Some claims are further drawn to incorporation methyl cellulose in the medium in amounts 210-5,000 mg/L or 1,900-2,500 mg/L or 2,205 mg/L. Some claims are further drawn to the medium osmolarity being from 300- 465 mOsm +/- 40 mOsm. Some claims are further drawn to the medium Brookfield viscosity at 20 °C in the range between 1-15 centipoises or 2.5-10 centipoises. Some claims are further drawn to incorporation of trace elements, amino acids, vitamins, pH buffer stabilizers into the medium. Some claims are further drawn to the exclusion of dextran.

The cited documents are relied upon as explained above for the disclosure of a preservation media for living organs, biological tissues and cells wherein all cited media comprises a liquid nutritive base, a high-molecular-weight HA and a sodium chloride in amounts as required by the claimed invention and wherein the media are free from components of animal origin as disclosed and wherein the media do not contain dextran. Moreover, the cited US 5,102,783 explicitly teaches substitution of HA for serum or for a component of animal origin for the benefit in reducing potential microbial and viral contaminations. The cited DERWENT publication XP 002036193 of JP 6107538 explicitly discloses that the exclusion of dextran provides for similar or superior effects as the HA-containing composition.

The medium of the cited DERWENT publication XP 002036193 of JP 6107538 is lacking additional components such as poloxamer 188 and methyl cellulose. But the other cited documents WO 96/32929 and US 5,102,783 (Alkemade et al) teach incorporation of additional viscosity agents and/or surfactants in the HA-containing medium for preservation and minimizing traumatic effects on living organs, biological tissues and cells. In particular, WO 96/32929 teach incorporation of additional viscosity agent such as methyl cellulose in the HA-containing medium. US 5,102,783 (Alkemade et al) teaches incorporation of additional viscosity agents or surfactants such as poloxamer 188 in the HA-containing medium.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to add poloxamer 188 and/or methyl cellulose to the HA-containing medium of the cited DERWENT publication XP 002036193 of JP 6107538 with a reasonable expectation of success in preserving and minimizing traumatic effects on living organs, biological tissues and cells because the prior art teaches and suggests incorporation of

additional viscosity agents and/or surfactants including poloxamer 188 and/or methyl cellulose in the HA-containing medium for preserving and minimizing traumatic effects on living organs, biological tissues and cells as adequately taught by WO 96/32929 and US 5,102,783 (Alkemade et al). Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

July 1, 2009

/Vera Afremova/

Primary Examiner, Art Unit 1657